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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,495	01/18/2006	Etienne-Emile Baulieu	03715.0148	7023
22852 7590 02/21/2008 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER CHUI, MEI PING	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 02/21/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/542,495

Applicant(s)

BAULIEU ET AL.

Examiner

MEI-PING CHUI

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) 4-8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 04/05/2006 and 01/18/2006.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 1-12 are pending in this application.

***Election/Restrictions***

2. Restriction is required under 35 U.S.C. 121 and 372:

This application contains the following inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-10 are drawn to a use of 3-methoxy-pregnenolone or a molecule derived from pregnenolone, and an excipient for the preparation of a drug to treat an acute lesion, a chronicle lesion or a degenerative disease.
  - II. Claims 11-12 are drawn to methods for increasing the stabilization and/or inducing the polymerization of the microtubules, or neuritic sprouting comprising 3-methoxy-pregnenolone.
3. The inventions I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking inventions I and II is the compound of 3-methoxy pregnenolone.

Chopp et al. (U.S. Patent No. 6,245,757) teach a pharmaceutical composition comprising pregnenolone methyl ether and a method of preparing said composition, as well as a method of treating ischemic damage to the brain by administering an effective amount of said composition in a suitable vehicle, wherein the composition comprising a progestin, i.e. pregnenolone methyl ether (it is identical compound as 3-methoxy-pregnenolone) and at least one excipients (Abstract: line 1-3; column 5, line 4-5 and column 6, line 1-2).

Since the technical feature linking each instant invention is known, it does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over prior art.

Accordingly, inventions I and II are not linked by the same or a corresponding special technical feature as to form a single general inventive concept.

### *Election of Species*

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

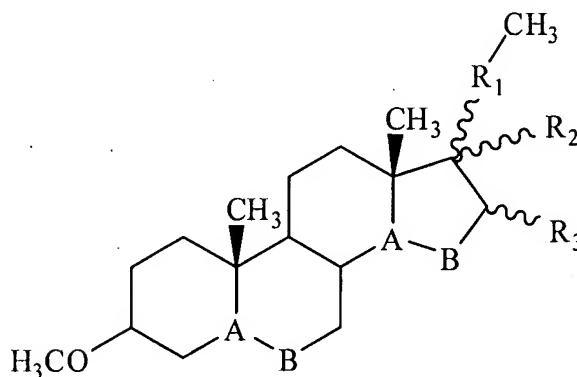
The species are each individual disease, recited in claims 1 and 2:

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Group (A): an acute lesion, a chronicle lesion or degenerative disease (claim 1);

Group (B): Alzheimer's disease, Parkinson's disease, age-induced memory loss, a cerebral lesion, a lesion of the spinal cord, and the disease recited therein (claim 2).

Group (C): 3-methoxy-PREG or a molecule derived from pregnenolone of formula (I), as recited therein in claim 1 (structure below):



These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking the species is **the compound of 3-methoxy-pregnenolone**. Chopp et al. (U.S. Patent No. 6,245,757) teach a method of treating

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ischemic damage of the brain or heart using a progestin, i.e. pregnenolone methyl ether. Therefore, in view of the teaching of the compound pregnenolone methyl ether in a method of treating brain or heart ischemia, this feature is not novel. Since the technical feature linking each instant invention is known, it does not constitute a special technical feature as defined by PCT Rule 13.2. The genus of an acute lesion, a chronicle lesion or a degenerative disease lacks unity of invention, *a posteriori*.

Accordingly, the individual species of an acute lesion, a chronicle lesion and a degenerative disease are not linked by the same or a corresponding special technical feature as to form a single general inventive concept.

5. Applicant is required, in reply to this action, to elect a single disclosed disease from Group B (or claim 2) and the type of lesion from Group A (or claim 1) in relation to the elected disease, as well as a single disclosed compound from Group C (claim 1), to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected disease, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The election of a species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

#### *Rejoinder Practice*

7. The examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a non-elected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims

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will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

#### ***Joint Inventorship***

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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9. A telephone call was made to Mr. Meyers on 01/25/2008 to request an oral election to the above restriction requirement and species.

### **DETAILED ACTION**

#### *Status of Action*

Applicant's response, on 02/11/2008, to the restriction requirement and the election of species requirement is acknowledged. Applicant elected, with traverse, invention I, which encompasses claims 1-10 in the reply. In response to the election of species, Applicants elected a cerebral lesion, which is a form of an acute lesion, as the elected disease and 3-methoxy-pregnenolone as the elected compound of formula (I). The traversal is on the ground(s) that the species of spinal cord lesion should also be examined together with cerebral lesion. This is not persuasive because a search for spinal cord lesion will require a different field of search than a search for cerebral lesion of the literature; thus constitutes a serious burden on the Examiner.

However, if applicant contents these two species are obvious variants, applicants must clearly states that on the record and upon doing so, the examiner will withdrawn the election of species.

*Status of Claims*

Accordingly, claims 1-6 and 8-10 are presented for examination on the merits for patentability as they read upon the elected subject matter, and claims 7, 11 and 12 are directed to non-elected inventions are withdrawn.

*Claim Objections*

Claims 4-8 are objected to under 37 CFR 1.75 (c) as being in improper forms because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

*Claim Rejections - 35 USC § 112 second paragraph*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-9** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in this rejection.

- (1) **Claims 1-8** provide for the “use” of 3-methoxy-pregnenolone; but the claims do not set forth any steps involved in the method/process, it is unclear what method/process

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applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. See MPEP, 2173.05(q).

**Claims 1-8** are also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See MPEP, 2173.05(q).

**Notes to the applicants:** once applicants amend the claims, restriction may be required depending on the amendment of the claims.

(2) **Claims 1-6 and 8** are rejected because they recite a term “aforementioned” of the drug. However, it is unclear whether this term “aforementioned” is referring to the limitation recites in the same claim or the limitation recites in its dependent claim. Thus, it renders the claims indefinite.

(3) **Claim 9** is rejected because it is unclear that the claim is directed to 3-methoxy-pregnenolone as a drug only or is directed to a composition comprising 3-methoxy-pregnenolone as a drug. Therefore, it renders the claim indefinite.

***Notes to the Applicants***

For the examination purpose, the examiner is construing the claims to be directed to a process of preparing a drug comprising 3-methoxy-pregnenolone, which is abbreviated as 3-methoxy-PREG, in the following rejection.

***Claim Rejection - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102(b) that form the basis for the rejections under this section made in this Office action:

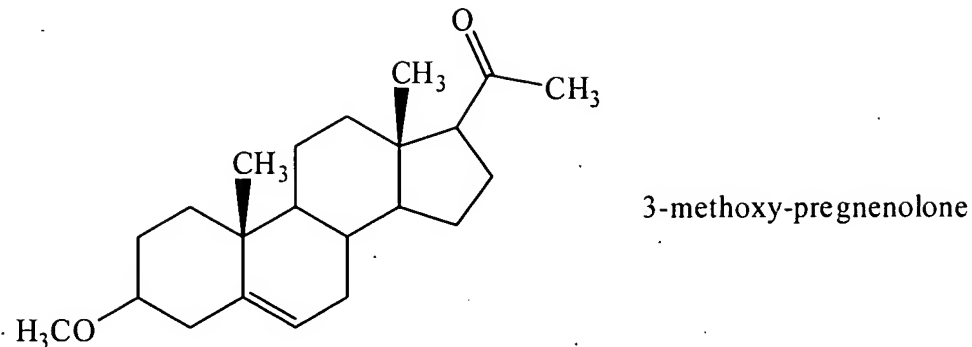
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

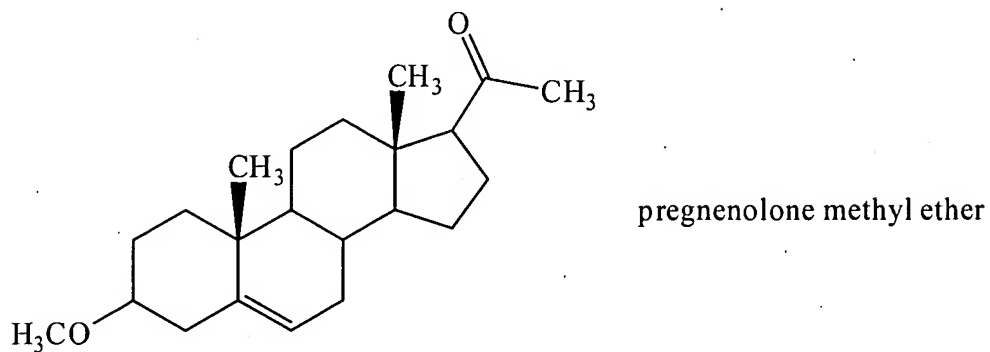
**Claims 1-6 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Chopp et al. (U. S. Patent No. 6,245,757).**

The instant claims 1-6 and 8-10 are directed to a process of preparing a pharmaceutical composition, in an injectable or an oral form, comprises 3-methoxy-pregnenolone (structure below) present in an amount of 50 to 2500 mg and an excipient:

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With respect to claims 1-3, 6, 9 and 10, Chopp et al. disclose a use of a progestin, i.e. pregnenolone methyl ether (structure below):



which facilitates rapid transport of a steroid to the brain, is effective in reducing infarct size following acute, focal ischemia, i.e. middle cerebral artery occlusion, when given before and after the onset of ischemia (column 3, line 63-67; column 4, line 1 and column 5, line 4). As a result, the ischemic tissues, including tissue of central nervous system or muscle tissue, can be

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treated so as to improve tissue survival and to hasten general bodily recovery (column 4, line 23-26).

Chopp et al. also disclose that the progestin is administered to a mammal in combination with one or more pharmaceutical excipients (column 6, line 1-2). More specifically, Chopp et al. disclose that the progestin compound is formulated to pass through the blood-brain barrier and enters the central nervous system at widespread sites (column 12, example 2: line 9-11).

Therefore, instant claims 1-3, 6, 9 and 10 are anticipated.

**With respect to claims 4 and 5**, Chopp et al. disclose that the progestin is formulated as a pharmaceutical dosage form, which is suitable for injection or orally administration (column 5, line 67 and column 6, line 43), or parenteral, i.e. intravenously (column 5, line 55-60). Therefore, instant claims 4 and 5 are anticipated.

**With respect to claim 8**, Chopp et al. also disclose that the pharmaceutical each dosage form comprises an active compound in amounts from 5 to 1000 mg (column 7, line 14-17). Therefore, instant claim 8 is anticipated.

With respect to the art rejection set forth above, the recitation of “makes it possible” in claim 3 is optional claim language. Further, applicants broadly claim “excipients” without any structural limitation. Therefore, it is the examiner’s position to interpret that any excipients taught in the prior art reads on claim 3, since the prior art and the claimed excipients are not structurally distinguish. In order to be limiting, the intended use must create a structural

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difference between the claimed composition and the prior art composition.. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

### *Conclusion*

No claims are allowed.

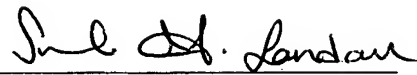
### *Contact Information*

Any inquiry concerning this communication from the Examiner should direct to Helen Mei-Ping Chui whose telephone number is 571-272-9078. The examiner can normally be reached on Monday-Thursday (7:30 am – 5:00 pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where the application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either PRIVATE PAIR or PUBLIC PAIR. Status information for unpublished applications is available through PRIVATE PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the

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PRIVATE PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Sharmila Gollamudi Landau", is positioned above a horizontal line.

Sharmila Gollamudi Landau

Primary Examiner

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